Remarks

This communication is in response to the Office Action dated **September 2, 2005**, wherein claims 17, 19, and 39-44 were rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement; and claims 17, 19, and 39-44 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 6,325,826 to Vardi et al (Vardi)

The following comments are presented in the same order and with paragraph headings and numbers corresponding to the Office Action.

Claim Rejections – 35 USC §112

(3-4)

In the Office Action claims 17, 19, and 39-44 were rejected under §112, first paragraph as failing to comply with the written description requirement. More specifically the Office Action asserts that the original specification fails to disclose "a single catheter having a single balloon for delivering a bifurcated stent assembly." The Office Action goes on to note that the specification does disclose "a stent or main branch stent including a body and a plurality of members extending from a side portion of the stent and a single balloon catheter delivery the main branch stent to a treated site." This rejection is respectfully traversed.

As described in the original specification, stents are well known implantable medical devices (see page 1, line 14 to page 3, line 8). Similarly, the concept of a bifurcation is known and understood (see page 3, line 9 to page 4, line 5). One of ordinary skill in the art will recognize a bifurcated stent as a stent which is suitable for deployment at a vessel bifurcation. One of ordinary skill will also recognize that a bifurcated stent will include a primary structure which defines a first lumen therethrough. Such a structure will further define at least one side opening in fluid communication with the first lumen. Some bifurcated stents will also be recognized by those of skill in the art to include additional secondary structure or structural elements extending from the primary structure, which further define the secondary opening or a secondary lumen extending therefrom.

With a basic understanding of stents and bifurcation concepts in mind, it is intuitively obvious that the device depicted in FIGs. 1 and 2 of the original Application is a bifurcated stent assembly. Scaffold 14 is clearly a structural component that defines a secondary

lumen or flow path 22. Flow path 22 clearly ***bifurcates*** from the primary flowpath 20. There can be no doubt that a stent having the features shown would be understood by one of ordinary skill in the art to be a bifurcated stent assembly as described in the original specification and the instant claims (see also page 10, lines 18-28).

Turning to FIG. 3 of the original Application, in FIG. 3 a single balloon is shown. In the specification, such a balloon is described as having a unique geometry which in the expanded configuration comprises a bulge region 34 that pushes against the members 24 of the scaffold 14 to deploy them. When employed on a catheter 42, the balloon 30 is used to deploy the stent 10 in the manner described above at bifurcation site 40 of vessels. When the stent is deployed by the balloon 30 of catheter 42, such as is shown in FIG. 6, the scaffold 14 extends into side branch vessel 46 of a vessel bifurcation 40 (see page 11, lines 8-28). Thus, the original specification fully describes "a single catheter having a single balloon for delivering a bifurcated stent assembly".

Claim Rejections – 35 USC §102

(5-6)

In the Office Action claims 17, 19, and 39-44 were rejected under §102(e) as being anticipated by Vardi. The Office Action states that Vardi discloses ***two*** catheters each with a single balloon. The Office Action goes on to state that "[T]the introductory statement of intended use and all other functional statements have been carefully considered but are deemed no to impose any structural limitations on the claims distinguishable over the Vardi et al's system which is capable of being used as claimed if one desires to do so."

In response Applicants assert that Vardi does not teach all of the elements of the instant claims.

As the noted in the Office Action Vardi discloses the use of two catheters each with a single balloon to deploy the stent and side branch (see figs 7-9 and column 8, lines 32-37). This is in contrast to the recitation of the instant claims wherein the bifurcated stent is deployed by ***only a single balloon*** of ***only a single catheter***. The recitation in the instant claims of a system having only a single catheter with a single balloon to deploy the stent is not merely "an introductory statement" or "a functional limitation" as asserted in the Office Action, but rather a

clear description of structural components of the system claimed.

Nowhere does Vardi describe a system employing a ***single*** catheter with a ***single*** balloon to deploy both the tubular stent and scaffold as recited in the instant claims. As recognized in the Office Action Vardi describes a system wherein ***two*** catheters are required to deploy the stent shown. As a result, the rejection is respectfully traversed.

Conclusion

In view of the foregoing it is believed that the present application, with claims 17, 19 and 39-44 is in condition for allowance. Early action to that effect is earnestly solicited.

Respectfully submitted,

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